



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

May 3, 1999

Betsy Codrea  
Regulatory Product Manager  
Gowan Company  
P.O. Box 5569  
Yuma, AZ 85366-5569

Re: Acknowledgment of Gowan's letter of April 19<sup>th</sup> regarding the chronic dietary endpoint for ODM

Dear Ms. Codrea:

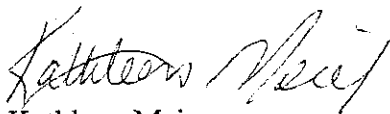
This letter is in response to Gowan's request for a clarification on the Agency's use of human data. As you may know, the Agency has been reviewing its policy on the use of human data. On December 10 - 11, 1998, a joint Science Advisory Board and Science Advisory Panel (SAB/SAP) held a meeting, which was open to the public, to discuss issues related to data derived from testing on human subjects and its use in pesticides risk assessments. The report that will come out of the SAB/SAP meeting will form the basis of a policy paper that will be available for public comment. A schedule has yet to be established for release of the policy paper.

As the policy is still in development, the Agency's decision on use of human data for ODM has not been finalized. However, the Agency will look at all human studies, existing and new studies, to see if they meet technical and ethical considerations. The ODM human study, MRID 00039839, is being reconsidered and will be discussed in a comprehensive Hazard Id memo that addresses the use of human data for all OP's. This document will be provided to you as soon as it becomes available.

Again, Gowan is encouraged to submit any new data as soon as possible if it is intended to be considered in the revised risk assessment. At this point, the Agency is already half way through the 90 day Agency time frame, and therefore we cannot guarantee the inclusion of additional data in the revised risk assessment.

The Agency will continue with the schedule agreed to by TRAC. As requested, Gowan's letter, along with this response, will be included in the public docket. If you have any further questions, feel free to call me, (703)308-8017.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kathleen Meier".

Kathleen Meier  
Chemical Review Manager  
Special Review and  
Reregistration Division